UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ROBERT CROCI, AS ADMINISTRATOR
OF THE ESTATE OF JOANN C. CROCI,
DECEASED,

Plaintiff,

Case No. 7:24-cv-02137-NSR

vs.

ZOLL MEDICAL CORPORATION
AND ZOLL SERVICES, LLC,

Defendants.
_____/

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

Defendants ZOLL Medical Corporation and ZOLL Services, LLC (collectively, "ZOLL" or "Defendants") move this Court to dismiss Plaintiff Robert Croci, as Administrator of the Estate of Joann C. Croci, Deceased's ("Plaintiff") Complaint. The Complaint asserts four claims: (1) negligence, (2) strict products liability, (3) breach of warranty, and (4) pecuniary losses to the estate. (*See generally* Compl.) In the Complaint, Plaintiff alleges that his late wife died as a result of an issue with the ZOLL LifeVest® wearable cardioverter defibrillator ("LifeVest") she was prescribed by her doctor. LifeVest is an FDA-approved, PMA Class III medical device. Because federal law preempts Plaintiff's claims, his claims lack sufficient factual support, and the claims also fail under New York state law, he fails to state a claim upon which relief may be granted. Therefore, his Complaint should be dismissed with prejudice.

FACTUAL BACKGROUND

This is a product liability action involving an FDA-approved, PMA Class III medical device: the ZOLL LifeVest® wearable cardioverter defibrillator ("LifeVest"). LifeVest is

designed and prescribed by physicians to protect patients at risk of sudden cardiac death. It is worn directly against the patient's skin, unlike other defibrillators which are implanted under the skin, and continuously monitors the wearer's heart rate and rhythm. It is lightweight and easy to wear, allowing patients to complete most normal daily activities with the protection of LifeVest. The LifeVest device contains sophisticated hardware components and circuitry and uses software algorithms to (1) detect certain abnormal heart rhythms – rapid ventricular arrythmias (ventricular tachycardia and ventricular fibrillation) – and (2) when appropriate, to deliver a treatment shock to help the heart return to a normal rhythm. It is used by thousands of people daily, around the world, and has been since its FDA approval in 2001.

Plaintiff claims that his wife, JoAnn Croci, was prescribed a LifeVest on March 16, 2023, following a heart attack. (Compl. ¶ 13.) Plaintiff alleges that in the two weeks that followed, Mrs. Croci contacted ZOLL twice for troubleshooting support related to her LifeVest. (*Id*. ¶¶ 17-18.) A ZOLL representative then went to Mrs. Croci's home to service her LifeVest. (*Id*. ¶ 18.) On April 8, 2023, Mrs. Croci went into cardiac arrest and later passed away at a nearby hospital. (*Id*. ¶¶ 3, 19.) Plaintiff alleges her LifeVest did not administer a treatment shock to prevent her death. (*Id*. ¶ 20.)

Following Mrs. Croci's passing, her surviving husband a Complaint in New York State Court on February 15, 2024, asserting four claims: (1) negligence, (2) strict products liability, (3) breach of warranty, and (4) pecuniary losses to the estate. (*See generally id.*) ZOLL removed the action to federal court in the Southern District of New York on March 21, 2024. (*See* Dkt. 1.) Following Plaintiff's Motion to Remand—that was denied on October 24, 2024—ZOLL sought leave to file a motion to dismiss, which the Court permitted. (*See* Dkt. 25, 26, 28.) ZOLL now files this timely Motion.

LEGAL STANDARD

A motion to dismiss under Federal Rule of Civil Procedure Rule 12(b)(6) is proper when Plaintiff's pleadings fail to state a claim upon which relief can be granted. When a plaintiff fails to plead "a plausible claim for relief" under Rule 8(a), dismissal should be granted. *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009). Plaintiff must provide a "short and plain statement of the claim" to show that he "is entitled to relief." Fed. R. Civ. P. 8(a)(2). While detailed factual allegations are not required, the Complaint must contain "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. This "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 545 (2007). "Factual allegations must be enough to raise a right to relief above the speculative level." *Id.* Naked assertions are insufficient. *Iqbal*, 556 U.S. at 678.

ARGUMENT

Plaintiff's Complaint should be dismissed under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim. First, Plaintiff's claims are expressly preempted (or in the alternative, impliedly preempted) by federal law because LifeVest has received FDA approval through the rigorous pre-market approval (PMA) process. Second, Plaintiff's claims also fail substantively under New York state law and do not meet the minimum pleading standards because they are vague and conclusory. Plaintiff's Complaint should therefore be dismissed with prejudice.

I. Plaintiff's claims are expressly preempted by federal law.

LifeVest is approved as a Class III medical device by the U.S. Food & Drug Administration ("FDA") under the Federal Food, Drug & Cosmetics Act ("FDCA"), 21 U.S.C. § 301 et seq. (*See*

Ex. 1, FDA PMA.[1]) Congress enacted an express preemption provision in the Medical Device Amendments ("MDA"), which requires that:

> [N]o State . . . may establish or continue in effect with respect to a device intended for human use any requirement—(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

Interpreting this provision, the Supreme Court articulated a two-part test in *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321 (2008), for courts to apply to assess preemption. First, a court "must determine whether the Federal Government has established requirements applicable to [the device]." *Id*. If it has, then the Court must determine whether Plaintiff's state law claims impose safety and efficacy requirements that are "different from, or in addition to," the federal requirements. *Id*. at 322 (citing 21 U.S.C. § 360k(a)). If yes, Plaintiff's claims are subject to preemption.

It is indisputable that the first part of this test is satisfied. The Federal Government established specific requirements for LifeVest, which is a Class III device that underwent the FDA's PMA process. *See id.* at 322–23 (explaining how the PMA process imposes specific requirements for each device). Claims involving a PMA device automatically satisfy the first *Riegel* condition.

[1] Available at https://www.accessdata.fda.gov/cdrh_docs/pdf/P010030A.pdf (last accessed Mar. 26, 2024). The Court may take judicial notice of publicly available FDA documents without converting a motion to dismiss to a motion for summary judgement. *See* Fed. R. Evid. 201(b)(2); *Gale v. Smith & Nephew, Inc.*, 989 F. Supp. 2d 243, 246 n.2 (S.D.N.Y. 2013) (taking judicial notice of premarket approval in FDA documents); *Bentley v. Dennison*, 852 F. Supp. 2d 379, 382 n.5 (S.D.N.Y.2012) ("Judicial notice of public records is appropriate—and does not convert a motion to dismiss into a motion for summary judgment—because the facts noticed are not subject to reasonable dispute and are capable of being verified by sources whose accuracy cannot be reasonably questioned.").

The second part of the test is likewise satisfied. In this part, the Court determines whether Plaintiff's claims would impose requirements that are "different from, or in addition to," the federal requirements and relate to safety and effectiveness. *Id.* at 322. In *Riegel*, the Supreme Court stated that "common law causes of action for negligence and strict liability do impose requirements and would be preempted by federal requirements specific to a medical device." *Id.* at 323–24 (citation omitted). Courts apply "Section 360k(a) broadly, preempting all manner of claims from strict products liability and negligence, to breach of warranty, to failure to warn and manufacturing-and-design-defect, to negligence per se." *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1152 (D. Minn. 2009), *aff'd*, 623 F.3d 1200 (8th Cir. 2010). *See also Otis-Wisher v. Medtronic, Inc.*, 616 F. App'x 433, 434 (2d Cir. 2015) ("Plaintiff's claims for strict liability failure to warn, strict liability design defect, and negligent failure to warn all seek to impose safety-related requirements on the device or its labeling beyond those imposed by the FDA."); *Simon v. Smith & Nephew, Inc.*, 990 F. Supp. 2d 395, 405 (S.D.N.Y. 2013) ("[D]esign defect claims regarding a PMA-approved device are squarely preempted by the MDA.").

Here, Plaintiff advances claims for negligence, strict liability, and breach of warranty. In his Complaint, Plaintiff repeatedly claims that LifeVest is "dangerous and defective." (Compl. ¶¶ 15, 26-27.) And he broadly alleges that ZOLL was negligent and is strictly liable for designing, testing, manufacturing, inspecting, packaging, marketing, labeling, selling, and servicing the subject LifeVest. (*Id.* ¶¶ 21, 27.) Plaintiff further offers a laundry list of thirteen actions ZOLL allegedly failed to take in relation to the subject LifeVest. (*Id.* ¶ 22.) In his breach-of-warranty claim, Plaintiff alleges that ZOLL expressly and impliedly warranted that its LifeVest was safe but breached that warranty by "designing and/or manufacturing and/or distributing and/or selling" a

product that was not safe. (*Id*. ¶ 37.) But each of these claims, if permitted, would impose requirements that are different from the federal government requirements applicable to this device. *Riegel*, 552 U.S. at 321. And each of these categories of activities is governed by the FDA's PMA of LifeVest and is subject to the FDA's continual oversight. Plaintiff's claims about each are therefore preempted unless he properly alleges a parallel claim—for example, a violation of federal regulations. *See Otis-Wisher*, 616 F. App'x at 434.

But Plaintiff fails to even attempt to allege valid parallel claims here. It is insufficient for a plaintiff to simply make conclusory allegations that a defendant's conduct violated FDA regulations to avoid preemption. *Simon*, 990 F. Supp. 2d at 403. "Rather, to state a parallel claim plaintiff must set forth facts pointing to specific premarket approval requirements that have been violated and link those violations to his injuries." *Id*. (quotations omitted); *see also Gelber v. Stryker Corp.*, 788 F. Supp. 2d 145, 155 (S.D.N.Y. 2011) (same).

Plaintiff's Complaint is bereft of any allegations that ZOLL somehow violated the FDA's regulations. Indeed, Plaintiff makes no reference to any federal requirements at all; he does not reference the FDA, federal law, or federal regulations at all in his Complaint. *See Gale v. Smith & Nephew, Inc.*, 989 F. Supp. 2d 243, 249 (S.D.N.Y. 2013) (holding claims preempted and failure to state a claim where the plaintiff did "not so much as reference the FDA, federal law, or federal regulation"). Further, Plaintiff here, like in *Gale*, does not "provide[] a factual basis for finding ZOLL violated federal law," nor does he allege "facts supporting an inference that [Mrs. Croci] was implanted [or provided] with products designed or manufactured in contravention of the FDA's premarket approval." 989 F. Supp. 2d at 249. Plaintiff altogether fails to allege ZOLL violated *any* federal requirements here. Thus, he fails to state any parallel claim that may avoid preemption. *See Otis-Wisher*, 616 F. App'x at 434 (dismissing strict liability and negligence claims

because they all sought to impose safety-related requirements beyond those imposed by the FDA). Accordingly, Plaintiff's negligence, strict liability, and breach of warranty claims are expressly preempted and should be dismissed.

II. Plaintiff's claims are impliedly preempted by federal law.

Moreover, even if Plaintiff's claims could somehow be found to be not expressly preempted under *Riegel*, they are impliedly preempted under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001). In enacting the FDCA, Congress declined to create a private right of action. Instead, it required that any action to enforce the FDCA "shall be by and in the name of the United States." 21 U.S.C. § 337(a). And Congress granted the FDA "complete discretion" in deciding "how and when [its enforcement tools] should be exercised." *Heckler v. Chaney*, 470 U.S. 821, 835 (1985).

In doing so, Congress left no doubt that only the federal government is authorized to bring a noncompliance action under the medical device provisions, not private litigants. *Buckman*, 531 U.S. at 349 n.4. Accordingly, any claim relying on the FDCA or its regulations "as a critical element" is impliedly preempted by § 337(a). *See Buckman*, 531 U.S. at 353; *In re Medtronic*, 592 F. Supp. 2d at 1161 ("Such a claim necessarily fails, because no private right of action exists under the FDCA."). Here, in the absence of a legitimate parallel claim, Plaintiff's allegations are an implicit attempt by a private litigant to enforce the FDCA, so they are impliedly preempted.

III. Plaintiff's substantive claims also fail to show he is legally entitled to relief under New York state law.

Preemption aside, Plaintiff's claims should also be dismissed because they substantively fail to state claims upon which relief may be granted. Overall, Plaintiff's Complaint provides little more than bare recitations of the basic elements for his claims without supporting facts. Indeed, Plaintiff's list of unspecific claims is so general that it could be copied and pasted into any

complaint involving any patient's use of a LifeVest. None of the allegations are specific to the subject LifeVest used by Mrs. Croci. None of them are specific to any particularly alleged defect. And none are specific to the alleged cause of Mrs. Croci's death. This vague, all-purpose list is plainly inadequate. Such conclusory allegations without plausible factual support fail to meet the minimum pleading standards. *Iqbal*, 556 U.S. at 678. Even so, if this Court were to rely upon what Plaintiff *has* pleaded, the substantive claims still fail.

a. Plaintiff's strict liability claim fails because it is vague, conclusory, and lacks adequate facts to show Plaintiff may prevail on its merits.

Plaintiff claims that ZOLL is strictly liable for designing, manufacturing, inspecting, testing, packaging, labeling, distributing, and selling its FDA-approved LifeVest device. But Plaintiff does not articulate the specific cause of action he is intending to advance under a strict liability theory. And his factual allegations do not reveal his intent. They offer little more than recitations of the basic elements of a strict liability claim without more detail. Such pleading deficiencies fail to put ZOLL on notice as to the actual claims Plaintiff intends to plead and thus makes it impossible for ZOLL to respond. *See Jemmott v. New York City Transit Auth.*, 660 F. App'x 62, 63 (2d Cir. 2016) ("[Rule 8's] purpose is to provide adequate notice of the claims so that the adverse party can answer the complaint and prepare for trial.").

i. Design defect

To the extent Plaintiff intends to plead that the subject LifeVest was defectively designed, his claim is squarely preempted as set forth above. However, the claim also should be dismissed for the additional and independent reason that it is insufficiently pleaded and lacks supporting facts to survive a motion to dismiss. "A defectively designed product is one which, at the time it leaves the seller's hands, is in a condition not reasonably contemplated by the ultimate consumer and is unreasonably dangerous for its intended use." *Reynolds-Sitzer v. EISAI, Inc.*, 586 F. Supp. 3d 123,

129 (N.D.N.Y. 2022). In New York, a claim for defective design must assert that: "(1) the product as designed posed a substantial likelihood of harm; (2) it was feasible to design the product in a safer manner; and (3) the defective design was a substantial factor in causing plaintiff's injury." *DiBartolo v. Abbott Lab'ys*, 914 F. Supp. 2d 601, 621 (S.D.N.Y. 2012). The first two prongs of these elements are functionally the risk utility test. *Id.*

Here, Plaintiff's Complaint fails to offer facts to support the required elements of this claim. "As to the first element, a plaintiff must identify a particular problem in the design of the allegedly defective device to survive a motion to dismiss under Rule 12(b)(6)." *Reynolds-Sitzer*, 586 F. Supp. 3d at 129–30. Plaintiff's Complaint fails to identify a "particular problem" in the design of LifeVest. And Plaintiff's Complaint completely fails to even suggest any alternative feasible design, which is required in New York. *Id.* ("[a] plaintiff must also plead facts alleging the existence of a feasible alternative design."). Because Plaintiff has failed to offer facts to show he is plausibly entitled to relief on a strict liability design defect under New York law, this claim should be dismissed.

ii. Manufacturing defect

To the extent Plaintiff intends to plead that the subject LifeVest was defectively manufactured, this claim is likewise insufficiently pleaded and lacks supporting facts to survive a motion to dismiss. In New York, a manufacturing defect claim requires "that a specific product unit was defective as a result of some mishap in the manufacturing process itself, improper workmanship, or because defective materials were used in construction, and that the defect was the cause of plaintiff's injury." *Colon ex rel. Molina v. BIC USA, Inc.*, 199 F. Supp. 2d 53, 85 (S.D.N.Y. 2001). If a "plaintiff has not alleged that the particular product administered to her had

a defect compared to other samples of that product," the manufacturing defect claim should be dismissed. *Miccio v. Conagra Foods, Inc.*, 224 F. Supp. 3d 200, 204 (W.D.N.Y. 2016).

Here, Plaintiff does not allege any facts that the particular LifeVest Mrs. Croci was provided had a defect that other LifeVests did not. Without factual allegations to support the existence of some manufacturing defect, this claim cannot survive. Dismissal is appropriate.

b. Plaintiff's negligence claim is legally insufficient for the same reasons as its strict liability claims.

Plaintiff also claims generally that ZOLL was somehow negligent in the distribution of the subject LifeVest, causing Mrs. Croci's death. In New York, negligence arises if "(1) the manufacturer owed plaintiff a duty to exercise reasonable care; (2) the manufacturer breached that duty by failing to use reasonable care so that the product was rendered defective; (3) the defect was the proximate cause of the plaintiff's injury; and (4) plaintiff suffered loss or damage." *DiBartolo*, 914 F. Supp. 2d at 611.

First, strict liability and negligence claims in product liability are nearly identical, so failure to support a claim with a lower bar—strict liability—necessarily means that a more stringent claim cannot simultaneously survive. *See Colon*, 199 F. Supp. 2d at 84; *DiBartolo*, 914 F. Supp. 2d at 623. Thus, because Plaintiff's strict liability claims failed to pass the pleading standard, so too does Plaintiff's negligence claim.

Further, Plaintiff's negligence claim—like his strict liability claim—is pleaded so broadly that ZOLL cannot discern which conduct Plaintiff deems negligent here. *See Jemmott*, 660 F. App'x at 63. Without more details about the specific causes of action Plaintiff believes entitle him to relief and plausible facts to support those claims, ZOLL is unable to adequately respond. Because of Plaintiff's pleading deficiencies and his failure to provide sufficient facts to support his claims, dismissal is necessary.

c. Plaintiff fails to allege sufficient facts to show he could legally prevail on his breach of warranty claim.

Plaintiff also alleges that ZOLL breached expressed and implied warranties related to the subject LifeVest. "An express warranty is an affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain." *Twohig v. Shop-Rite Supermarkets, Inc.*, 519 F. Supp. 3d 154, 167 (S.D.N.Y. 2021) (quoting N.Y. U.C.C. § 2-313(1)(a)). But Plaintiff points to no express warranty nor express language warranting anything about LifeVest. He generally states that ZOLL warranted to Mrs. Croci, and the general public, that its LifeVest was designed and manufactured without defect and was reasonably safe for foreseeable uses. (Compl. ¶ 26.) But Plaintiff does not provide any facts about where or how such warranty was provided. And privity is required for a breach of warranty claim. *See Titlebaum v. Loblaws, Inc.*, 407 N.Y.S.2d 307, 308 (N.Y. App. Div. 1978) ("[L]ack of privity is a legitimate defense to a products liability action based on breach of warranty."); *Fish v. Tom's of Maine, Inc.*, 705 F. Supp. 3d 72, 81 (N.D.N.Y. 2023) (explaining that New York law requires privity for breach-of-warranty claims). Without facts to support the existence of an express warranty between Mrs. Croci and ZOLL that was breached, this claim cannot survive.

Plaintiff similarly fails to make sufficient allegations that ZOLL breached any implied warranty. "A breach of the implied warranty of merchantability occurs when the product at issue is unfit for the ordinary purposes for which such goods are used." *Twohig*, 519 F. Supp. 3d at 167 (citing N.Y. U.C.C. Section 2-314(c)). Again, Plaintiff fails to allege facts that the subject LifeVest was not of merchantable quality or did not conform to any promise or affirmation of fact made on its label. *See Twohig*, 519 F. Supp. 3d at 167. Accordingly, Plaintiff has failed to offer facts to show he may plausibly prevail on his breach of warranty claim.

In addition, pre-suit notice of a breach of warranty is required in New York. *See Wheeler v. Topps Co., Inc.*, 652 F. Supp. 3d 426, 433 (S.D.N.Y. 2023) (explaining that N.Y. U.C.C. § 2-607(3)(a) requires a buyer to provide notice of the breach or be barred from remedy). Plaintiff does not allege any facts that he provided pre-suit notice to ZOLL, and thus, his warranty claim is barred for that additional and independent reason.

IV. Pecuniary losses

Because Plaintiff's substantive claims fail, his fourth claim for pecuniary losses to the Estate also fails. Plaintiff claims that, based upon the claims for negligence, strict liability, or breach of warranty, he is entitled to compensation for economic losses. (Comp. ¶ 42.) But Courts have held that pecuniary losses are derivative and therefore are not recoverable without a cognizable injury. *See Horn v. Med. Marijuana, Inc.*, 80 F.4th 130, 137 (2d Cir. 2023) ("[P]ecuniary loss flows from, or is derivative of, an antecedent personal injury." (quotation omitted)); *Kotary v. Spencer Speedway, Inc.*, 47 A.D.2d 127, 129, 365 N.Y.S.2d 87, 89 (1975) ("An action by a parent to recover pecuniary loss sustained by reason of injuries inflicted upon his child is derivative in nature to the extent that it depends upon the right of the child to recover for his injuries."). Accordingly, Plaintiff's fourth claim fails and should also be dismissed.

CONCLUSION

Plaintiff's Complaint fails to state any plausible claim against ZOLL. Not only are his claims expressly and impliedly preempted under federal law, but they are also substantively vague, conclusory, and lacking adequate factual support. Accordingly, ZOLL respectfully requests that the Court dismiss Plaintiff's Complaint in its entirety with prejudice.

Dated: January 3, 2025
Minneapolis, MN

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing was served by Email on January 3, 2025 on the following:

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